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January 23, 2002

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Washington, D.C. 20231

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Sale Ref: 00000004 DAW: 070153 09671540
01 FC:117 R20.00 CH

U.S. Patent Application Serial No. 09/671,540

Timothy W. King

Filed: September 27, 2000

Our File: 121117-1000

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Sale Ref: 00000003 DAW: 070153 09671540
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Void

Enclosed for filing in connection with the above-referenced patent application are the following documents:

1. Response to Office Action; and
2. Return postcard.

Please file the above-referenced document and return the date-stamped postcard to our office at the above address. It is believed that no additional fee is due. If this is incorrect, the Commissioner is hereby authorized to charge any fees due which may be required by this paper to Deposit Account No. 07-0153.

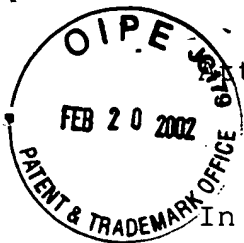
In the meantime, if you have any questions or comments concerning any of the above, please call the undersigned at your convenience. Otherwise, please accept the enclosed.

Respectfully submitted,
Gardere Wynne Sewell LLP

Matthew E. Burr
MEB:eaz
Enclosure

cc: Sanford E. Warren, Jr. (w/o enclosure)
Timothy W. King, M.S., Ph.D. (w/enclosure)
Charles W. Patrick, Jr., Ph.D. (w/enclosure)

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PATENT

Attorney Docket No.: 121117-1000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Timothy W. King

Charles W. Patrick

Serial No.: 09/671,540

Filing Date: September 27, 2000

Art Group: 1615

Examiner: Amy Pulliam

Title: Compositions and Methods for
Biodegradable Microspheres as Carriers
of Bioactive Substances

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I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope, with sufficient postage, addressed to: Commissioner for Patents, Washington, D.C. 20231 on January 23, 2002.


Signature

Commissioner for Patents
Washington, DC 20231

RESPONSE TO OFFICE ACTION

Dear Sir:

This is a response to the Official Action, dated October 23, 2001, due for response on or before **January 23, 2002** for the captioned patent application. Applicants respectfully request that the provisional election submitted herewith be entered in the present case and that the traverse submitted herewith be considered. Applicant believes that no fee is due for this response. However, if this is incorrect, please charge any required fees to our Deposit Account No. 07-0153.

ELECTION/RESTRICTION

Restriction was required under 35 U.S.C. § 121 to one of the following inventions:

- I. Claims 1-18, 23 and 24, drawn to method for making microspheres, classified in class 427, subclass 212.
- II. Claims 19-22, drawn to a system for delivering a therapeutic agent to tissue, classified in class 424, subclass 489.
- III. Claims 25-36, drawn to microspheres, classified in class 424, subclass 489.

Applicants provisionally elect, with traverse, the claims of Group III, claims 25-36 for prosecution on the merits.

TRAVERSE

Applicants respectfully traverse the Election/Restriction requirement on the grounds that the Examiner has not made a *prima facie* case. Additionally, Applicants respectfully submit that the efficiency and expediency of prosecution will be enhanced by withdrawal of the Election/Restriction requirement.

Every requirement to restrict has two aspects, (1) the reasons (as distinguished from the mere statement of conclusion) for why the invention as *claimed* are either independent or distinct, and (2) the reasons for insisting upon restriction therebetween. MPEP § 808. [Emphasis in the original]. With regard to the first aspect, The Examiner

failed to provide a reason as to why the inventions identified in the Official Action are distinct.

The reasons under MPEP § 808 given by the Examiner for insisting upon exercising her authority under 35 U.S.C. § 121 to require restriction must be reasons approved by the Commissioner. The reasons approved by the Commissioner are set out in MPEP § 803: (1) the inventions must be independent (see MPEP § 802.01, § 806.04, § 808.01) or distinct as claimed (see MPEP § 806.05 - § 806.05(i); and (2) there must be a serious burden on the examiner if restriction is not required (see MPEP § 803.02, § 806.04(a)-(j), § 808.01(a) and 808.02). Examiner must provide reasons and/or examples to support conclusions. MPEP § 803.

For purposes of the initial requirement, a serious burden on the examiner may be shown, *prima facie*, if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in MPEP § 808.02. That *prima facie* showing may be rebutted by appropriate showings or evidence by the applicant. MPEP § 803.

Applicant respectfully submits that the Examiner has failed to make a *prima facie* case that restriction is required. The reason provided in the Official Action to which this reply is responsive as to why the inventions as claimed are either independent or distinct fails to address the invention *as claimed*. The Official Action asserts that microspheres may be made in several ways. The claims, however, are directed toward the *Applicants'* method for making microspheres. Applicants' method provides a product that has advantages over microspheres made by other methods. For

example, Applicants' microspheres have the ability to encapsulate solid protein that is biologically active - a feature that microspheres made by other methods do not have. Applicants' product, therefore, cannot "be made by another and materially different process." Accordingly, Applicants respectfully submit that the *prima facie* requirements of MPEP § 803 have not been met.

Further, the Action failed to establish that a serious burden would be imposed on the Examiner if restriction were not required. The Examiner failed to establish that separate fields of searching would be required. That is, the Examiner failed to establish that, even if the inventions may be classified in the same class and subclass (as with the claims of Groups II and III), a complete search would require examination of other classes and subclasses that differ for each distinct invention, thereby imposing a burden on the Examiner if all the inventions were examined in the same application. The Examiner failed to establish that the distinct inventions have achieved a separate status in the art, even though Group II and Group III are classified together. MPEP § 802. Although the claims of Group I are classified by the Examiner in a different class and subclass from Groups II and III, Applicants respectfully submit that the searching required for examination of all the claims as originally filed would not impose a *serious* burden on the Examiner.

Prosecution expediency would be served by withdrawal of the Election/Restriction requirement due to Applicants' right to seek Rejoinder.

Where the application as originally filed discloses the product and the process for making and/or using the product, and only claims directed to the product are presented for examination, when a product claim is found allowable, applicant may present claims directed to the process of making and/or using the patentable product by way of amendment pursuant to 37 CFR 1.121. In view of the rejoinder procedure, and in order to expedite prosecution, applicants are encouraged to present such process claims, preferably as dependent claims, in the application at an early stage of prosecution. Process claims which depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance. MPEP § 821.04.

Applicants have elected product claims but have disclosed the process for making and using the product. Pursuant to Rejoinder practice, Applicants would be entitled to Rejoinder of the claims for making and using the product (that is, all of the non-elected claims) upon allowance of a product claim. Withdrawal of the restriction requirement would save the Applicants the time and expense of petitioning for Rejoinder and would result a better examined patent because all the claims would be examined, not just the product claims (because Rejoinder is an entitlement the Rejoined claims are not examined on the merits).

Additionally, since elected claim 25 depends from non-elected claim 1, claim 25 would have to be amended to be put

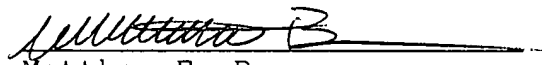
in condition for allowance. Such amendment would be unnecessary if the restriction requirement were withdrawn. Applicants, therefore, respectfully request withdrawal of the restriction requirement and prosecution of the claims as originally filed.

CONCLUSION

Applicants provisionally elect the claims of Group III for prosecution on the merits, with traverse. For the reasons set forth above, Applicants respectfully request reconsideration by the Examiner and withdrawal of the Election/Restriction requirement. Applicants submit that claims 1-36 are fully patentable. Favorable consideration and allowance of the application is therefore respectfully requested. If the Examiner has any questions or comments, or if further clarification is required, it is requested that the Examiner contact the undersigned at the telephone number listed below.

Dated: January 23, 2002

Respectfully submitted,
GARDERE WYNNE SEWELL LLP


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